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| APPLICATION NUMBER | FILING DATE | FIRST NAMED APPLICANT | ATTORNEY DOCKET NO. |
| 08/476,567         | 06/07/95    | WILSON                | R CARRPR-0022C3     |

18N2/0428

EXAMINER  
GUZO, P

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ART UNIT  
1805PAPER NUMBER  
8DATE MAILED:  
04/28/97

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

## OFFICE ACTION SUMMARY

Responsive to communication(s) filed on 1/30/97

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire Three (3) month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

Claim(s) 35 and 39-42 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 35 and 39-42 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

Notice of Reference Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). 7

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

- SEE OFFICE ACTION ON THE FOLLOWING PAGES -

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A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 35 is provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 56 of copending application Serial No. 08/302,241. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

This rejection is repeated for reasons of record in the previous Office Action (Paper #4). Applicants indication that they are willing to cancel claim 56 from the 08/302,241

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application upon indication of allowable subject matter is acknowledged.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 39-40 are rejected under 35 USC 112, 1st paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

This rejection (with regard to enablement) is maintained for reasons of record in the previous Office Action and for reasons outlined below. As a result of applicants' amendment filed 1/30/97, the rejection is applied to new claims 39-40.

Applicants traverse this rejection by citing *Hybridtech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 USPQ 81 (Fed. Cir. 1986) with respect to a "...patent need not teach, and preferably omits, what is well known in the art". Applicants indicate that the art with respect to use of hybridization probes, hybridization conditions and stringency were extremely

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well known in the art and cite a passage from Lewin's *Genes IV*, 1990. Also, applicants indicate that they did supply a relevant prior art reference with regard to hybridization conditions in the IDS filed 7/24/95 (the Maniatis *Molecular Cloning* manual section describing hybridization conditions). Applicants assert that it would have been routine for the skilled artisan to modify hybridization conditions to accomplish different objectives. Finally, applicants indicate that their description of Southern hybridization conditions in the context of analyzing the presence or amplification of GS-specific sequences could be easily adapted to a diagnostic assay.

1. Applicant's arguments filed 1/30/97 have been fully considered but they are not deemed to be persuasive.

The key question in this rejection is whether the instant specification provides the skilled artisan with the teachings necessary to make and use the invention without having to practice undue experimentation. Applicants assert that the skilled artisan would have been able to supply the necessary teachings to enable the claimed invention from his or her knowledge of the prior art with regard to hybridization and diagnostic assays. In this regard, the Court has recently provided guidance as to the content of an enabling disclosure. In *Genentech Inc. v. Novo Nordisk A/S* 42 USPQ2d 1001, (Fed. Cir. 1997), the Court indicates:

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"It is true, as Genentech argues, that a specification need not disclose what is well known in the art. See, e.g. *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986). However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. However, when there is no disclosure of any specific starting material **or of any of the conditions under which a process is to be carried out** (emphasis added), undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill in the art. It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement"

Clearly, in this case, the instant specification only provides the suggestion to develop diagnostic methods of detection of GS in samples (using unidentified "conditions of appropriate stringency") without elucidation of any of the actual experimental conditions necessary for the actual enablement of said methods. Applicants appear to be relying on the knowledge of the skilled artisan to supply the critical (enabling) details of the claimed methods; therefore the specification must be considered non-enabling.

With regard to applicants' statement that the examiner was incorrect in stating that applicants have not provided citations of relevant prior art documents for hybridization methods, it is noted that the examiner indicated that no citations of relevant prior art documents were provided in the instant specification since it is the specification which must provide the teachings

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and guidance (with regard to citations of any prior art documents) necessary for the skilled artisan to practice the claimed invention. The citation of prior art documents (i.e. the Maniatis reference) in an IDS cannot compensate for a non-enabling disclosure.

With regard to applicants' indication that the skilled artisan could use Southern hybridization experiments (recited in the context of measuring gene amplification) to develop diagnostic assays, it is noted that applicants have provided no guidance on how one of skill would ascertain the hybridization conditions for any specific diagnostic assay, what types of biological samples would be used to provide nucleic acids to be assayed, what type of disease conditions would be examined, etc. It must be concluded therefore, that the skilled artisan would have need to practice undue and excessive experimentation in order to enable the claimed invention.

2. Claims 39-42 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 39-40 are vague in the recitation of the term "appropriate stringency" since it is unclear how one would

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ascertain what the "appropriate" stringency conditions are for any given sample.

Claims 41-42 are vague in that they depend from cancelled claims.

No Claims are allowed.

3. Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo whose telephone number is (703) 308-1906. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, George Elliott, can be reached on (703) 308-4003. The fax phone number for this Group is (703) 308-0294.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 3087-0196.

David Guzo  
April 25, 1997

  
DAVID GUZO  
PRIMARY EXAMINER  
GROUP 1800